Model for Local Federal/State Planning and Coordination of Field Operations and Training for Facility Inspections

A Partnership for Food Protection "Best Practice"

Produced by: the Partnership for Food Protection National Workplan Workgroup October 2013, updated 2024

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I. Introduction

Domestic mutual reliance (DMR) is a seamless partnership that enables the FDA and states with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and regulatory actions to meet the public health goal of a safe national food supply.

The planning and coordination of field operations and training, and effective communication between the U.S. Food and Drug Administration (FDA) and other federal, state, local, tribal, and territorial counterparts (hereinafter partner agencies) with overlapping jurisdiction are critical components of an integrated food safety system (IFSS). These activities advance DMR by facilitating the efficient use of limited government resources and promote the safety and security of the food supply in an IFSS.

Planning and coordination of field operations as referenced in this document relate to the scheduling of inspections, sample collection and analysis; and executing assignments, response activities, and compliance/enforcement actions.

While a National Work Plan for Food Facilities and a National Food Sampling Surveillance System are long term goals of the FDA and partner agencies collectively, responsibility for building an IFSS, local FDA District and partner agency planning, and coordination of field operations are an achievable short-term goal. Best practices for carrying out such planning and coordination of field operations as well as associated training serve as a basis for this document. FDA Division level/partner agency planning and coordination efforts for field operations should be reflective of the strategic priorities and work planning efforts of the individual entities and should be conducted at the local level where these operations can be actively coordinated and accomplished. Personnel from partner agencies involved in such planning and coordination efforts should be FDA commissioned and/or have an appropriate 21CFR 20.88 agreement in place.

This document is a PFP "Best Practice" and, as such, is intended to provide suggestions that should be considered by FDA Divisions and partner agencies in their planning and coordination activities. Not all suggestions will be applicable in every situation, however, should be considered where appropriate for the effective coordination of activities and leveraging of resources.

Suggested Prerequisite Discussions/Activities to Planning and Coordination Efforts

For successful work planning and coordination to occur, there are some basic requirements and activities that need to be addressed in advance of such efforts. FDA Division and partner agencies should meet regularly with appropriate senior managers and program staff to discuss the topics listed below and complete some or all of the activities. It is suggested that these discussions/activities occur prior to actual FDA/partner agency work planning.

Topics/activities include, but are not limited to:

Discussion Points	Activities to Complete
Review Facility Inventories and Identify any focal areas or specialized Information Including After Hours commodities needing attention	1. Share key personnel contact information including after-hours contact numbers

	2. Assure appropriate individuals are commissioned, and/or agencies are signed up through a 21CFR 20.88 3. Establish communication protocols 4. Establish joint goals and objectives 5. Develop an inspection plan to make best use of existing resources while minimizing duplication of efforts
Staffing Issues/Resource & Budgetary Constraints	1. Identify staff training needs and gaps 2. Discuss any contract issues (within scope of partner's authorities)
Information Sharing Procedures	1. Discuss compliance trends and triggers, regulatory strategies, and identify enforcement tools available to each partner and compliance triggers 2. Establish routine communication channels for operational and management staff 3. Discuss Continuity of Operations in the event of an emergency
Illness/Outbreak Trends	1. Coordinate resources
Risk Categorization	1. Coordinate sampling and identify analyzing lab
Laboratory Capacity & Support	1. Include the laboratory when discussing sample collection plan 2. Coordinate sample collection and analysis – route, timeframe, and surge capacity with the laboratory 3. Laboratory will evaluate testing capabilities and limitations

An environment of trust and collaboration between staff is essential to facilitate effective FDA/partner agency field operations and training planning and coordination. Senior leaders in each organization need to set the tone and support the use of time for such efforts and as resources permit, the travel necessary for staff to meet and develop a professional rapport.

Open, honest and timely feedback regarding the conduct of inspections and/or work quality between the FDA Division and respective partner agencies is paramount. To work effectively together and establish a fruitful relationship, FDA and partner agency managers must be open to feedback regarding themselves, their respective staff and work products, and must strive for continuous improvement.

Inspection Work Planning and Facilitation of Related Ongoing Communications

The Food Safety Modernization Act (FSMA) provides mandated minimum frequencies for the inspection of high risk and non-high-risk food and feed facilities. Many states also have laws that provide inspectional frequency mandates that do not coincide with the federal requirements. As a result, FDA and its partner agencies may target the same firms for inspection in a 12-month period through independent inspection planning efforts. Joint planning and coordination of inspections provides a mechanism to leverage limited resources and eliminate, where appropriate, the independent conduct of inspections by FDA/partner agencies within the same general timeframe.

Strategies for successful joint FDA/partner agency inspection work planning and to facilitate related ongoing communications include:

1. Annual inspection work planning meetings should be conducted between FDA Division and partner agencies (in person or virtually) with overlapping jurisdiction regarding food facility inspections. These annual meetings should be supplemented by additional meetings (in-person or virtual) to discuss progress, problems, and issues as necessary to facilitate continuous communication, and to ensure adjustments are made, when appropriate, to the inspection work plan throughout the year.
2. The staff attending inspection work planning meetings should be personnel from each agency responsible for coordination of work plan assignments within their given programs.
3. The respective agencies should share the inventory of firms that each plan to inspect, prior to the meeting date, to make the meeting as efficient as possible. FDA should also share a list of potential state contract inspection firms, if applicable.
4. During the work planning meetings, the firms that both FDA and the partner agency have targeted for inspection should be discussed to determine which agency will conduct the inspection that year and/or to determine if a joint inspection is warranted. Factors to consider when making such determinations include: the compliance history of the firm, which agency might be most effective in gaining compliance, geographic location relative to staff availability, staff expertise and experience, the risk profile of the firm, the established FDA/partner agency inspection frequency for that firm, and which agency did the last inspection to assure that a facility is viewed with "new eyes" or a different inspection approach. If, for some reason, both FDA and the partner agency need to independently inspect the same firm during a given year, they should consider scheduling the inspections 5-7 months apart. The goal should be to minimize the number of instances that FDA and a partner agency inspect the same firm in a 12-month period unless there is a specific reason to do so.
5. A single reconciled inventory listing the firms to be inspected by each agency and the anticipated quarter(s) of the year when the inspection will occur should be prepared at the conclusion of the annual work planning meeting and shared among the FDA and the partner agency in a timely manner.
6. Periodic follow-up meetings and/or teleconferences should occur between the FDA and partner agencies to ensure that inspection work plan objectives are on track for timely completion and to allow for inspection assignments to be realigned based on competing priorities. Unplanned work arising out of natural disasters, outbreaks, and other programmatic needs will occasionally arise and should be addressed through modification of the planned activities.
7. To facilitate ongoing communication on inspections conducted by FDA Divisions and partner agencies, copies of Inspectional Observations/Notices of Violation (FDA 483 or equivalent) and basic information about the inspection (establishment inspection report or equivalent) should be provided to the other agency, after redaction if needed, within 30 days of completion of the inspection. The general information can be incorporated into a standardized form or through the export of data from the respective program's database.

The sharing of this core information allows the respective agencies to update their databases with relevant information about the facilities operation and compliance for use in risk- based assignment or work planning activities.

8. Ongoing communications and coordination will need to occur relative to complaints. More specifically, consumer or industry complaints should be evaluated upon receipt and assigned as appropriate. Complaints involving significant product defects, injuries, tampering, or product contamination should be shared between the FDA Division and partner agencies with overlapping jurisdiction. Coordination of follow-up activities or determination of the lead agency in a follow-up investigation should be made by the respective program leads and then carried out as discussed and agreed upon.
9. Methods to routinely share lists of new food manufacturing firms or firms that are determined to have relocated or to be out of business (using FDA's definition) should also be developed and implemented. Periodic queries of the program's respective databases could yield concise lists of these firms with key contact information that can be shared with relevant partners.

Sampling Planning and Coordination

FDA and state partner agencies routinely collect surveillance samples or conduct targeted sampling activities to monitor foods for microbiological and chemical hazards. The purpose of this surveillance may be for monitoring compliance with regulations or guidance action levels, monitoring commodities frequently implicated in foodborne outbreaks, or conducting signals evaluation.

Strategies for successful sample work planning discussions should include the following:

1. Developing surveillance sampling plans

- Inclusion of key laboratory personnel in the development of an annual sampling work plan will facilitate laboratory coordination with field operations, provide for technical input on sampling strategies, and provide advanced notice of reagent and supply purchasing needs.
- State regulatory program and laboratory partner participation in annual Human Food Program (HFP) workplan prioritization request open season to submit commodity-hazard pairs for consideration in the upcoming FDA workplan or Laboratory Flexible Funding Model (LFFM) cooperative agreement product testing track commodity/hazard pairs is important to ensure state interests are represented in these workplans.
- Sample collection and analytical resources are defined for FDA Divisions in the annual FDA work plan. State partners may have a sampling plan under the LFFM, Animal Food Regulatory Program Standards AFRPS Standard 11, and/or other state surveillance sampling plans for human food regulatory programs.
- When developing and sharing individual agency or joint sampling plans, include specific commodities, quantity of samples to collect, targeted analyses, sampling schedule, laboratory resource availability, appropriate laboratory methodologies.
- FDA and partner agencies should develop an understanding of laboratory capacity, surge capacity, and method capabilities so appropriate planning can occur to ensure a smooth flow of samples and completion of analyses in a variety of events or situations.

2. Inter-agency coordination of surveillance sampling plan

- Sharing respective sampling work plans, including state LFFM sample plans, other state surveillance, and FDA Division sampling assignments and planned SCOPE sampling for the year.
- Identifying opportunities for joint or coordinated sampling efforts between the Human/Animal Feed (HAF) Division and state partner agencies. If a state receives samples collected by FDA for analysis or otherwise contributes to FDA work plan sampling, results must be submitted through the Food Safety DX (FSDX) sample data sharing to ensure all FDA work plan samples are available in FDA's sample database.
- Discuss and identify procedures for notification and communication of violative sample results between FDA and partner agencies. In reviewing the planned sampling for the year, each agency should consider and discuss in advance what the individual agency and joint response would be to a violative sample. FDA and partner agencies should discuss any additional requirements that either agency would have for utilization of resulting analytical data for compliance or enforcement activities including sample size/subsampling, collection location, analytical methodologies, and laboratory certification or accreditation. For LFFM sampling conducted by the state, notification/communication/follow-up processes are in the LFFM Sample Guide and the State Regulatory Program-lab agreement. Annual review/approval of sampling plans addresses the discussion of expected agency actions and response posture.
- Discuss and identify procedures for communication of aggregate surveillance analytical results between the FDA and partner agencies. All sample analyses need to be reported in such a way to inform future programs priorities, policies, and risk assessments by the receiving partner. There should be discussion about what format of surveillance sampling data is easiest for each partner agency to receive, review, and use for their purposes. For state partners sharing aggregate surveillance sampling collection and analytical data with FDA (other than LFFM), use of Food Safety (FS)DX sample data sharing is recommended, to support Agency risk assessments and policy decisions including the establishment of action levels. For LFFM sampling conducted by the state, there are established processes for reporting positive samples and aggregate surveillance data (quarterly), these are outlined in the LFFM Sample Guide.

3. Addressing unplanned sampling needs

- Should unplanned sampling needs be identified during the year, these needs should be communicated to the HAF Division and state regulatory program management, to address as resources permit. If the state participates in LFFM, a pivot request may be submitted under LFFM. FDA will use its internal processes to notify HFP of any deviation from the work plan to address a local need. HFP will be invited to be part of the work planning and sampling priority discussion throughout the process. It is recognized that use of FDA resources must align with FDA's risk-based priorities (e.g. most significant contaminants list, high risk foods list).

Compliance and Enforcement Planning and Coordination

Local planning, coordination, and communication regarding non-compliant firms are critical to facilitate public health protection. It is the shared responsibility of all regulatory agencies with jurisdiction over a particular firm to assure their respective partners are fully aware of non- compliant conditions at the firm and to work collaboratively to develop appropriate actions to address the conditions utilizing the most effective and efficient tools available at the local, state, and federal level.

1. FDA and partner agencies should have a good understanding of each other's enforcement authorities/tools and limitations, responsibilities, capabilities, and protocols including enforcement triggers for pursuing compliance actions against multi- jurisdictional or interstate operations.

2. When FDA or a partner agency identifies major non-compliance issues with a regulated firm, a standardized agreed upon procedure for prompt notification of the other agency (within 24 hours) should be implemented.
3. Key compliance personnel from FDA and the respective partner agencies should schedule regular teleconferences or meetings to share information about ongoing major compliance actions being undertaken by the respective agencies. The concept of a joint compliance/enforcement team approach should be supported and encouraged by state and federal managers.
4. When complex compliance problems are identified, FDA Divisions and partner agencies in consultation with their legal and compliance staff, when appropriate, should decide which organization has the most effective immediate compliance/enforcement tools to bring about correction of the violation and which organization has the most effective long-term strategy to ensure ongoing compliance. Coordinating enforcement actions (such as inviting the partner agency to attend office hearings) or proceeding jointly against operations operating in violation of the law (one utilizing a short-term enforcement approach and the other utilizing a longer-term approach) shows a united front and provides the most effective protection to the food supply.
5. Warning letters and other enforcement documents (i.e. permanent injunctions, civil penalty assessments, etc.) generated by either FDA or the partner agency should be routinely discussed and shared.

Training Plan Coordination

FDA Manufactured, Animal Food, and Retail Food Program Standards require the establishment of a training program and staff auditing process to verify effective knowledge transfer of training materials and effective implementation of the regulatory inspection process among partner agency personnel. Annual training coordination meetings (or meetings held in conjunction with the scheduled annual inspection work planning meetings) should be conducted to identify and prioritize training needs. These meetings will help in developing plans for co-training opportunities or cross-training of agency personnel by partner agencies. Strategies for planning and coordinating training activities should include:

1. Partner agencies should engage in a discussion of training gaps and needs, prioritization of training courses that should be delivered in the coming year, and training reciprocity. A multi-year training plan should be developed to support scheduling and delivery of core training and continuing education throughout the year. Training needs and plans should be reviewed and updated on an annual basis and shared with the FDA's Office of Domestic Partnerships (ODP).
2. If an agency has concerns over the level of training of partner agency personnel to conduct certain activities, partners should discuss a mutually agreeable plan to achieve as much training uniformity as possible.

Geographic Based Projects Coordination

Periodically, various trends related to contamination of commodities or food-borne illness outbreaks occur that necessitate FDA and partner agencies to take a closer look at individual commodities or industries to identify prevalence or incidence of contamination, identify possible risk or contributing factors to contamination, assess the need for updating guidance, or to assess compliance with existing rules. Often these projects may be geographically or regionally based, related to growing regions for the commodities or other environmental factors. Any specialized or commodity specific inspection and/or sampling assignments developed to address these concerns, should be shared and discussed between partner agencies. Strategies for coordinating geographic based projects should include:

A. Discussing the need for such projects at annual work planning meetings or on an ad-hoc basis as the need arises. The discussions may include considerations for high-risk food products, emerging hazards, environmental events and trends, and specific Center for Veterinary Medicine (CVM) or HFP field assignments.

B. Before geographic based projects are undertaken, a general plan for coordinating inspection and/or sampling activities should be established and should consider resource needs and modifications to pre-existing work plan activities or goals to allow sufficient time to address the project objectives. Divisions will discuss such plans with the appropriate FDA HFP and the Office of Inspections and Investigations (OII) management including availability of resources and priority versus other assignments that may be forthcoming on a national level.

C. When sampling activities are planned, laboratory personnel and HFP staff should be included in the discussion to facilitate laboratory coordination with field operations, provide technical input on sampling strategies, and provide advanced notice of reagent and supply purchasing needs.

Preparedness and Response Coordination

Emergency situations/incidents involving foodborne outbreaks, tampering, or product adulteration usually require the activation of response assets within the respective agencies. Proper preparedness for response is critical to ensure effective protection of the food supply and consumers. The FDA's Coordinated Outbreak Response and Evaluation plus Emergency Preparedness (CORE+EP) Network and Rapid Response Team Best Practices Manuals offer a good roadmap for procedural development and response initiation.

1. FDA Division and partner agencies with overlapping jurisdiction should periodically meet to coordinate response and communication strategies for various types of emergency events. This will allow all parties involved in the response activities to become familiar with each other and exchange contact information before the emergency occurs. Triggers for response, Continuity of Operation Plans (COOP), and Food Emergency Response Plans (FERP) should be shared and discussed to ensure each agency has a full understanding of their role and appropriate legal authorities.
2. FDA Divisions and partner agencies may wish to establish Memorandums of Understanding (MOU) to delegate authorities and establish a pool of resources that can be tapped into during emergency events including ICS procedures.
3. FDA Divisions and partner agencies that intend to initiate a response to an event should notify their counterparts so that either a coordinated response can be initiated or that the other agencies with jurisdiction are at least made aware of planned activities. Regular updates should be provided to keep the partners up to date on activities and findings.
4. FDA Divisions and partner agencies that plan to coordinate response activities should ensure that all key personnel receive the necessary specialized training to carry out their duties and that response staff periodically participate in multi-jurisdictional tabletop exercises.
5. Principal staff involved in recall activity oversight from the FDA Division and partner agencies with overlapping jurisdiction should convene an annual face-to-face meeting to discuss recall issues and to establish real time communication and coordination strategies regarding recall activities.
6. FDA Division and partner agencies should coordinate recall activities, Reportable Food Registry (RFR) report follow-ups and recall effectiveness checks on recalls and RFRs of mutual interest to eliminate duplication and provide for the broadest coverage available.
7. FDA Division and partner agencies should share information about recalls initiated and/or monitored by their respective agencies with partner agencies as they arise. Recalls referred to the FDA Division from outside the state should also be shared with partner agency program recall coordinators as they arise.

8. Recall coordinators should share distribution, trace back / trace forward information, and recall effectiveness check data, in compliance with confidentiality requirements, as it received or as agreed upon by the partner agencies.

Considerations for Coordination with Partners with Different Inspectional Activities

Not all partner agencies inspect the same entities as FDA. For example, local agencies are often responsible for the regulation of retail food facilities while FDA has jurisdiction over retail food facilities. The agency does not routinely inspect these facilities because state and local agencies typically fill that role. However, communication and coordination of relevant activities is still important and must be fostered and supported to ensure effective coverage of the food supply throughout the food chain. Considerations should be given to:

1. Ensuring local and tribal partners have appropriate 21 CFR 20.88 agreements in place so that non-public documentation can be shared during critical events.
2. Ensuring coordination of training activities to local programs and that the local agency's staff receives the training necessary to carry out their duties.
3. Establishing communication strategies to share information about FDA and state activities with local partners, and coordinating food safety activities that need to be conducted at the retail level. FDA and partner agencies should establish strategies for communication with local agencies during disasters, major recalls, or other events that have an impact on local communities or retail food facilities.
4. Providing access to technical assistance on retail food safety issues.

Implementation of the Model Procedure

Implementation of planning and coordination for field operations and training as described in this document require investments in time and resources to conduct such activities; the development and refinement of associated processes; and a commitment to continual improvement over time. Initial meetings to address prerequisites such as communication strategies, legal authorities, and jurisdictions must occur before effective planning and coordination activities can get underway.

Implementation Plan/Metrics

A proposed phased in implementation plan of the best practices identified in this document for Divisions and partner agencies and associated metrics for year one implementation follows:

Implementation Plan

<u>Year 1</u>

- Prerequisite Meeting(s)
- Self-assessment: determine where there are gaps in work planning and coordination Inspectional Work plan initiation.
- Sampling Coordination Initiation
- Compliance and Enforcement Coordination Initiation

<u>Year 2</u>

- Continue Developing Year 1 Objectives Training Plan Coordination Initiation
- Geographic Based Project Coordination Initiation

Year 3 and Ongoing

- Continue Developing Year 1 and 2 Objectives Preparedness and Response Coordination Initiation

Possible Metrics for Year One Implementation

1. Partner agencies met to discuss work planning at least two times during the 12-month period and at least one of those meetings was held face to face.
2. Agency performed self-assessment and developed a plan for integration of activities outlined in this best practices document;
3. Partner agencies shared their respective food inventory lists during the 12-month period.
4. Partner agencies developed and implemented a strategy for communicating and coordinating compliance activity follow-up actions at firms with overlapping jurisdiction.
5. Partner agencies initiated a process to share inspectional findings, including FDA 483 and State Notice of Violation, data within 30 days of completion of the inspection; and
6. Partner agencies count the number of joint enforcement actions within a given year and the effectiveness of those actions in gaining compliance in a facility.